DEPARTMENT OF HEALTH & HUMAN SERVICES Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Center - WO66-G609
Silver Spring, MD 20993-0002

November 13, 2014

Krishna Imports Inc.
Dba Stephens Instruments
c/o Ms. Archna Johnson
Vice President
2500 Sandersville Rd.
Lexington, KY 40511

Re: K140352
Trade/Device Name: VeraPlug™ Punctal Plug
Regulation Number: Preamendment
Regulation Name: Preamendment
Regulatory Class: Unclassified
Product Code: LZU
Dated: October 3, 2014
Received: October 6, 2014

Dear Ms. Johnson,

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Division of Industry and Consumer Education at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Industry and Consumer Education at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

Kesia Y. Alexander -S

for Malvina B. Eydelman, M.D.
Director
Division of Ophthalmic and Ear,
Nose and Throat Devices
Office of Device Evaluation
Center for Devices and Radiological Health

Enclosure

DEPARTMENT OF HEALTH AND HUMAN SERVICES
Food and Drug Administration

Indications for Use

Form Approved: OMB No. 0910-0120
Expiration Date: January 31, 2017
See PRA Statement on last page.

510(k) Number *(if known)*
K140352

Device Name
VeraPlug

Indications for Use *(Describe)*

The VeraPlug™ Punctal Plug is for use in patients with dry eye syndromes.

Type of Use *(Select one or both, as applicable)*

☒ Prescription Use (Part 21 CFR 801 Subpart D) ☐ Over-The-Counter Use (21 CFR 801 Subpart C)

PLEASE DO NOT WRITE BELOW THIS LINE – CONTINUE ON A SEPARATE PAGE IF NEEDED.

FOR FDA USE ONLY

Concurrence of Center for Devices and Radiological Health (CDRH) *(Signature)*

510(K) Summary

Date Prepared	November 5, 2014
510K #:	K140352
Applicant:	Krishna Imports Inc dba Stephens Instruments 2500 Sandersville Rd. Lexington, KY 40511
Contact Person:	Archna Johnson
Phone No.:	855-857-0518, 859-259-4926 (fax)
Device Name:	VeraPlug™ Punctal Plug (Punctal Occluder)
Common/Usual Name:	Plug, Punctum
Type of Submission:	Traditional, Original
Product Code:	LZU
Regulatory Class:	Unclassified

Indications for Use:

The VeraPlug™ Punctal Plug is for use in patients with dry eye syndromes.

Device Description:

The VeraPlug™ Punctal Plug is designed to provide reduction or elimination of tear drainage through the inferior or superior puncta, thus maintaining lubricating tears on the surface of the eye. Each VeraPlug™ Punctal Plug is molded from medical grade silicone. The VeraPlug™ Punctal Plug is available in 3 sizes (small, medium, and large) and is packaged 2 per/box. Each plug is sterile and preloaded on an inserter.

The inserter is manufactured using medical grade ABS (acrylonitrile butadiene styrene), and 304 stainless steel.

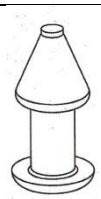
Predicate Devices/Substantial Equivalence:

The Lacrivera VeraPlug™ is equivalent to the predicate device listed below:

Predicate Device:

Odyssey Medical	Punctal Occluder (#K972523)

Predicate product Comparison Table

Parameter	Stephens Instruments	Odyssey Medical	Comment
510(k) Number	K140352	K972523	
Indications for Use	The VeraPlug™ Punctal Plug is for use in patients with dry eye syndromes.	Punctal Occluders (plugs) are indicated for the treatment of "dry eye" syndrome. Dry eye being a condition where there is sufficient lubrication in the eye and the conjunctive becomes much less moist than normal. This produces pain and discomfort in the eyes. This may occur in any condition that causes scars of the cornea, such as erythema multiforme, trachoma, or corneal burns, etc. Other patients that may benefit are: cataract patients, patiens with arthritis, patients medicated for hypertension, contact wearers of any age, seasonal allergy sufferers, patients who liver in dry climates, or spend extended periods in air conditioning, and any others who suffer from dry eye irritatio. Treatment is to stop tear outflow via a specific punctum to enhance tear contact time in certain dry eye conditions. It is also reasonable that eyes drops of many kinds would be more effective if retained on the surface of the eye, rather than drained into the sinus.	Both are intended for use with patients suffering from dry eye syndromes
Shape Design			Plugs are comparable in nose diameter, overall length, and shape design
Material	Medical Grade Silicone	Medical Grade Silicone	Same
Sterile	Yes	Yes	Same
Nose Diameter			
Small	0.76mm	0.75mm	Within cleared nose diameter ranges
Medium	0.89mm	0.88mm	
Large	1.02mm	1.01mm	
Overall Length			
Small	1.65mm	1.63mm	Within cleared overall length ranges
Medium	1.83mm	1.80mm	
Large	2.00mm	1.93mm	
Stretch Test Comparison Study Results	Passed	Passed	Same
Patient Population	Patients suffering from dry eye syndromes	Patients suffering from dry eye symptoms	Same

Discussion of Technological Characteristics

The VeraPlug™ Punctal Plug and the predicate device are both intended for use with patients suffering from dry eye syndromes. There are slight design differences between the Odyssey and Stephens Instruments punctal plugs. Both have a similar design shape with a conical shaped nose (distal end), a shaft, and a dome shaped proximal end, with comparable nose diameters and overall lengths. Both are manufactured of medical grade silicone and packaged 2 per/box. Each plug is sterile, preloaded on an inserter.

Non-Clinical Tests

The non-clinical testing performed on the Lacrivera VeraPlug™ included sterility testing which was completed via a validated ETO (Ethylene oxide) sterilization cycle and bench testing that included a simulated implantation stretch test. Biocompatibility testing for the plug was determined to be unnecessary as the material utilized in the plug, medical grade silicone, has a long standing history of being biocompatible for use for the manufacture of punctal occluders. The processes utilized by manufacturers in the forming of the plug are also common throughout the industry.

Standards utilized for testing include:

- ISO 11135-1:2007 Sterilization of Health Care Products – Ethylene Oxide – Part 1: Requirements for the Development, Validation, and Routine Control of a Sterilization Process for medical devices
- ISO 11737-1:2006 Sterilization of Medical Devices – Microbiological Methods Part 1: Determination of the Population of Microorganisms on Product (Bioburden Testing)
- ASTM F-1980-07 Standard Guide for Accelerated Aging of Sterile Barrier Systems for Medical Devices
- ISO 11607-1 ISO Packaging for Terminally Sterilized Medical Devices – Part 1: Requirements for Materials, Sterile Barrier Systems and Packaging Systems (Bubble Test, Dye Penetration)
- ISO 11607-2 Packaging for terminally Sterilized medical Devices – Part 2: Validation Requirements for Forming, Sealing and Assembly Processes
- ISO 10993-7:2008 Biological Evaluation of medical devices – Part 7: Ethylene Oxide Sterilization residuals (ETO Residuals)

Conclusion

The Lacrivera VeraPlug™ is substantially equivalent to the predicate device in intended use, material, design and device specifications. Safety and performance testing was performed on the sterilization method, ethylene oxide residuals, microorganisms on the product and post-accelerated aging package validation. The results of which have demonstrated that the device

does not introduce significant questions of safety or effectiveness and therefore, is substantially equivalent to the predicate device.